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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,667	02/10/2004	Gregory B. Altshuler	105090-0233	3788
21125	7590	12/12/2005		
			EXAMINER	
			JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/776,667	ALTSHULER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Henry M. Johnson, III	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 March 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-42 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 14 June 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>020705 012805</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 1 implies a chromophore may store radiation in a cumulative manner until activated, yet no mention of this property is disclosed. The disclosed time between sessions is 1 to 30 days, making it unclear how the applied chromophore would remain in the oral cavity in a viable manner for a 24 hour period.

### ***Claim Objections***

Claim 7 is objected to because of the following informalities: the examiner believes the "1400000 nanometers" cited is in error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 24-25 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the radiation step dosage being lower than that required to activate the chromophore, therefore, repeating the step also will not activate the chromophore.

Claims 5 and 6 are indefinite for citing a power density improperly. Power densities related power to an area.

Claim 24 recites the limitation "the target region" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "the target region" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 is unclear as written.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,942,658 to Rizou et al. Rizou et al. teach a method for whitening teeth, the steps comprising, Applying a whitening gel to the teeth to be treated, directing a laser light at the teeth using a laser power density of  $3 \text{ W/cm}^2$ , activating the laser for 15 seconds, waiting for a period of about 1 minute and repeat the radiation steps a further three to ten times depending on the condition of the patient's teeth (Col. 8, lines 20-30). The power levels are within those cited by the applicant and, lacking any specific means for determination of chromophore activation, are interpreted as a low dose. The whitening gel is disclosed as having a target chromophore (Col. 7, line 18) and an antibacterial agent (Col. 7, line 49). The wavelength of the radiation is taught as 700 to 11000 nanometers (Col. 6, lines 8-10).

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Claims 19-23 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,879,159 to Cipolla. Cipolla teaches a method for whitening teeth by radiating with a broadband light source. Xenon arc sources as taught are well known to have wavelengths exceeding 200 to 1000 nanometers. Cipolla discloses that in particular, light in the blue/green spectrum, is beneficial in tooth whitening procedures because light in this wavelength tends to be more readily absorbed by yellow/brown colored stain molecules but mostly reflected by the red colored tooth pulp in vital teeth (Col. 1, lines 45-48), thus teaching the stain molecules as chromophores.

Regarding claims 21-23, the type or location of a stain has no impact on the method steps.

Regarding claims 27 and 28, an endogenous agent is inherently in the target and has no impact on the method steps.

Regarding claims 32-34, the only active step is photoactivating, a mere irradiation of a target. The results are not cited as related to any specific fluence or wavelength to differentiate them from the basic photoactivation step. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Claims 35, 37-41 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2003/0152528 to Singh et al. Singh et al. teach hydrogel compositions for tooth whitening using a hydrogel (paragraph 0114) that forms a polymeric matrix (paragraph 0047). The hydrogel composition may be light activated (paragraph 0020) and is capable of adhering to a tooth surface (paragraph 0022). The thickness is disclosed as

from 80 to 800 microns (paragraph 0113) and the composition may include a plasticizer (paragraph 0025).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizoiu et al. as applied to claim 1 above, and further in view of U.S. Patent 6,106,293 to Wiesel. Rizoiu et al. is discussed above, but does not disclose a film carrier. Wiesel teaches a tooth whitening method using a carrier for the agents. The carrier may be stored in a sterile package in a rolled tape form or in differently sized strips (Col. 3, lines 43-46). The strips or tape are interpreted as a film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the carrier film as taught by Wiesel in the method of Rizoiu et al. as such carriers are common and well known in the art.

Claims 17, 18 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizou et al. as applied to claim 1 above, and further in view of U.S. Patent 6,106,293 to Wiesel. Rizou et al. is discussed above, but does not disclose application of radiation to heat the treated area. Wiesel teaches, in addition to applying the compound and irradiation, exposing the strip to virtually any light source in order to further accelerate heating of the peroxide, thereby accelerating the whitening of the teeth. The light source, for example, may be a heat lamp, a carbon dioxide laser, any short or long wave infrared laser, an argon laser, an ultraviolet laser, or a Yttrium Arsenic Gallium (YAG) laser (Col. 3, lines 13-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the heating as taught by Wiesel in the method of Rizou et al. as heating is common to enhance a reaction.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0152528 to Singh et al. Singh et al. is discussed above, but does not disclose a matrix of ethylene oxide. Singh et al. teach many materials for the matrix including ethylene compositions. No specific properties or unexpected results are cited by the applicant for ethylene oxide and it is therefore considered an obvious design choice by one skilled in the art.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,879,159 to Cipolla in view of U.S. Patent 6,525,819 to Delawter et al. Cipolla is discussed above, but does not disclose measurement of tooth whiteness. Delawter et al. teach a colorimeter for dental applications that measures the color and reflectance of a tooth (Col. 1, lines 15-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of measuring color as taught by Delawter et al. in the

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method of Rizoiu et al. as an alternative to the manual comparison of colors as suggested by Delawter et al.

***Allowable Subject Matter***

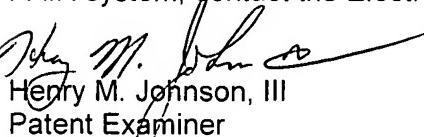
Claims 10-17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry M. Johnson, III  
Patent Examiner  
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